K111392

page 1 of 1

WOOJEON ACUPUNCTURE NEEDLE

5. 510(k) Summary

NOV - 4 2011

1. **Applicant**
Woojeon Co.
364-4 Dangjeong-dong, Gunpo-si, Gyeonggi-do 435-832, Korea
TEL. +82 (31) 456-5050
FAX. +82 (31) 455-2919
Date: Aug. 29th,2011

2.Contact person

Peter Chung
-Tel 412-687-3976,Fax #: 412-687-3976 (Same with the home number)
-Mobil phone #: 412-512-8802)
-300 Atwood Street Pittsburgh, PA 15213 USA

3. Device Name

Trade Name: . WOOJEON ACUPUNCTURE NEEDLE

Common Name: Single use, Acupuncture Needle.

Classification Name: Single use, Acupuncture Needle.

Product Code: MQX

Regulation: 880.5580

Class of device : ClassII.

4. Predicate Devices

WOOJEON ACUPUNCTURE NEEDLE is similar with the legally marketed ASIA-MED Single use, Acupuncture Needle to have K052085.

5. Description of the Device

The our needles are sterile which are inserted into specific points on the skin, called "acupuncture points." The Acupuncture Needles are manufactured from stainless steel and sterilized with gamma irradiation.

The Acupuncture Needles are available in 78 models as per diameters (0.16 to 0.40 mm) and 78 needle tube models as per lengths (8-60mm)

6. Intended Use:

WOOJEON ACUPUNCTURE NEEDLES is intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states

7. Technical Characteristics

The Acupuncture Needle is examined microscopically and mechanically tested to evaluate pull-out and elasticity properties. Specifically, the surfaces of the subject and predicate devices were found to be smooth and free of visible defects at 200-300X magnification. Also, the pull-out force of the Acupuncture Needle was quantified and fell within the average values reported for the predicate devices. Finally, the elasticity properties of the subject device were found to be substantially equivalent to the predicate devices

8. Safety and Effectiveness

The Acupuncture Needle is a safe and effective device and is substantially equivalent to the predicate devices listed in this 510(k) submission; that is, the Acupuncture Needle has the same intended use (i.e., indications for use) and is similar, and in some cases the same, in both design (e.g., materials, sizes) and performance. Any differences in technological characteristics between the Acupuncture Needle and the predicate devices do not raise issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Woojeon Company
C/O Mr. Peter Chung
300 Atwood Street
Pittsburgh, Pennsylvania 15213

NOV - 4 2011

Re: K111392
Trade/Device Name: Woojeon Acupuncture Needles
Regulation Number: 21 CFR 880.5580
Regulation Name: Acupuncture Needle
Regulatory Class: II
Product Code: MQX
Dated: September 29, 2011
Received: October 19, 2011

Dear Mr. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): k111392

Device Name: Woojeon Acupuncture Needles

Indications For Use:

WOOJEON ACUPUNCTURE NEEDLES is intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states

Prescription Use __X_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) 11/3/11

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111392